510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEC 2 3 2009

APPLICANT:	Notal Vision Ltd.
TRADE NAME:	Foresee Home™
COMMON NAME:	Perimeter
CLASSIFICATION NAME:	Automated perimeter
DEVICE CLASSIFICATION:	Class I
PRODUCT CODE:	HPT
PREDICATE DEVICE:	Preview PHP™

SUBSTANTIALLY EQUIVALENT TO:

510K	TRADE OR PROPRIETARY NAME	MANUFACTURER
K050350	Preview PHP™	Notal Vision Ltd.
K063609	River 1	SHL Telemedicine International, Ltd.
NA	*Amsler Grid Chart*	*NA*
K053303	Commander III	Cardiocom
K071564	Motiva	Philips Medical Systems

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Foresee Home system is an interactive software driven device that provides a series of linear images to the macular and peri-macular region of the eye. The changes in macular and near macular function can be quantified by the device thus enabling the reader to detect early changes in macular degeneration and associated diseases to allow earlier intervention.

The Foresee Home applies the concept of the static and automated perimeter in the detection of visual field defects. The technology, based on hyperacuity, is used for highly specific quantification of central and paracentral visual fields defects. Hyperacuity (also termed "Vernier acuity") is defined as the ability to perceive a difference in the relative spatial localization of two or more visual stimuli. Hyperacuity threshold may be as low as 3-6 sec of arc and the hyperacuity stimuli are highly resistant to retinal image degradation and thus suitable for assessing retinal function in patients with opaque media as well. Retinal pigment epithelium (RPE) elevation, such as that

which occurs in AMD, causes a shift in the regular position of photoreceptors. It is hypothesized that such a shift causes an object to be perceived at a different location from its true location in space.

The analysis engine of the device tries to define areas in the visual field that are suspected as being related to CNV. Such areas are called CNV related zones. Although these zones are called 'CNV-related,' they simply indicate areas of greater metamorphopsia and can often occur in non-CNV lesions."

Note that the response on this indicator is only indicative of the presence or absence of significant metamorphopsia that may exist in conditions NOT associated with CNV (such as geographic atrophy or drusen).

The Foresee Home is intended to be used in a home environment following training given by a qualified healthcare professional. The user interface and interaction with the device is similar to office Preview PHP. The results of each testing session, the test reports, similar to these generated by the Preview PHP system, will be transmitted electronically directly to the healthcare professional.'Test reports will not be displayed on the monitor in the patient's home, but rather will be used by the healthcare professional in the same fashion as it is currently employed with the in-office Preview PHP. Thus, the only difference between the Preview PHP system and the Foresee Home is that the Foresee Home unit is placed in the patient's home environment to facilitate testing and the test report is then transmitted to the healthcare professional.

It should be noted that the Foresee Home is not intended to provide automated interpretation, evaluation, treatment decisions, or to be used as a substitute for professional healthcare judgment.

INDICATION FOR USE

The Foresee Home is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration, as an aid in monitoring progression of disease factors causing metamorphopsia including but not limited to choroidal neovascularization (CNV). It is intended to be used at home for patients with stable fixation.

TECHNICAL CHARACTERISTICS

The technical characteristics of the Foresee Home are similar to the Preview PHP (K050350).

PERFORMANCE DATA

Since the results of testing of the Foresee Home results are similar to those of the Preview PHP, the performance. i.e., percent positive agreement and percent negative agreement of the Foresee Home, are also similar to the performance of Preview PHP (K050350).

The clinical study submitted in K050350 for the Preview PHP was designed to validate that that the minimal percent positive agreement and minimal percent negative agreement are greater than 80%. The study results demonstrated that the percent positive agreement was 81.5% and percent negative agreement was 87.7%. The Preview PHP results were compared to the gold standards, i.e., color fundus photographs and fluorescein angiographies.

This 510K addresses the ability of the system to be used in home environment. The Foresee Home usability study showed that after clinic training, 98.5% of the users were capable of performing the test by themselves.

Comparison between unsupervised test in a home simulated environment and supervised test in the clinic showed correlation of 93.85%, indicating that the test results are similar no matter if the examination was supervised at the clinic or performed without assistance by the users at their home environment.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The technological characteristics and testing results of the Foresee Home in home use are similar to these of the predicate device, the Preview PHP, cleared under K050350.

The Amsler Grid has similar intended use: to rapidly detect central and paracentral irregularities in the visual field.

Data transfer is accomplished by means of a telemedicine module that is substantially equivalent to the Motiva Monitor Device, cleared under K071564. Additional predicate devices are included and offer similar collection and transmission of health related information from the patient's home to health care professionals; these include the River I telemedicine system (K063609) and the Commander III (K053303).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Notal Vision Ltd
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
733 Bolsana Drive
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DEC 2 3 2009

Re: K091579
Trade Name: ForeSee Home
Regulation Number: 21 CFR 886.1605
Regulation Name: Perimeter
Regulatory Class: Class I
Product Code: HPT
Dated: November 2, 2009
Received: November 3, 2009

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

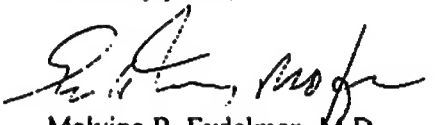
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091579

Device Name: Foresee Home™

Indications for Use:

The Foresee Home is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration, as an aid in monitoring progression of disease factors causing metamorphopsia including but not limited to choroidal neovascularization (CNV). It is intended to be used at home for patients with stable fixation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091579